



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/270,437 | 03/16/1999 | YAO-TSENG CHEN | LUD5538.1CIP | 2508 |

24972 7590 06/04/2002

FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER

CANELLA, KAREN A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 06/04/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/270,437

Applicant(s)
Chen et al

Examiner
Kar n Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-108 and 110-142 is/are pending in the application.
- 4a) Of the above, claim(s) 74-79 and 85-107 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 110-128 and 131-142 is/are allowed.
- 6) ☒ Claim(s) 80-84, 108, 129, and 130 is/are rejected.
- 7) ☒ Claim(s) 54-73 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Notice to Comply

Art Unit: 1642

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 53 and 109 have been canceled. Please note that the amendment filed February 26, 2002 directed the cancellation of claims 53 and 109 and the entry of new claims 110-144. However, claim 128 was followed by claim 130, and the final new claim was numbered as claim 143. Under Rule 126, claims 130 to 143 were renumbered as claims 129 to 142. Applicant states that claims 110 to 143 will be pending. However, claims 60 to 108 remain pending as the amendment directed only the cancellation of claims 59 and 109. Therefore, claims 54-108 and 110-142 are pending. Claims 74-79 and 85-107 remain withdrawn from consideration. Claims 54-73, 80-84, 108 and 110-142 are under consideration.

Claim Rejections Withdrawn

3. The rejection of claims 54-73, 80-84 and 108 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific substantial asserted utility or a well-established utility, is withdrawn. Applicant argues that it was unlikely that the antibodies in cancer patients were binding to E coli proteins. This was not the intended argument presented by the examiner. Paper No. 12, section 5, page 4, lines 2-25 state "under conditions of recombinant expression, epitopes of KOC-2 and 3 which are not normally expressed in a patient within the context of MHC could be expressed by E. Coli. If one of these epitopes cross-reacts with allogenic patient serum, it cannot be concluded with certainty that the protein is expressed in said patient". It is clear that the examiner was not arguing that an E coli protein epitope was cross reacting with the antibody, but an epitope of KOC-2 or KOC-3 that was not normally presented in the context of MHC in a human subject. It is well known in the art that certain sequence motifs restrict the peptides presented by MHC in human cells (Falk et al, Nature, 1991, Vol. 351, pp. 290-296;

Art Unit: 1642

Ruppert et al, Cell, 1993, Vol. 74, pp. 929-937; Rotzschke et al, Nature, 1990, Vol. 348, pp. 252-254; Bjorkman et al, Nature, 1987, Vol. 329, pp. 512-518; and Traversari et al, Journal of Exp Med, 1992, Vol. 176, pp. 1453-1457). As the peptides presented by E coli in the SEREX assay are not restricted by the sequence motifs, it is likely that numerous peptides will be present on the surface of said E coli that would not be present on the surface of human cancer cells. However, applicants arguments regarding the presence of antibodies in cancer patients that bind with the KOC polypeptides versus the absence of antibodies which bind to said polypeptides in normal individuals is persuasive.

4. The rejection of claims 54-73, 80-84 and 108 under 35 U.S.C. 112, first paragraph, for the reasons of record stated in section 7 of the Office action mailed June 5, 2001, are withdrawn.

Claim Rejections Maintained

5. The rejection of claims 80-84 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons of record set forth in section 8 (B) of the Office action mailed June 5, 2001. Applicant has not provided an argument to render moot this rejection.

6. The rejection of claims 108 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention due to the absence of sequence compliance is maintained, as the CRF submitted February 26, 2002 was found to be damaged. Please see the attached CRF Problem Report.

Newly added claims 129 and 130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

Art Unit: 1642

and/or use the invention. This application contains sequence disclosures in the specification and in the claims, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 since the CRF does not include SEQ ID NO:9-14.

Applicant is given the response period of this office action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Applicant is requested to return a copy of the attached Notice to Comply with the reply.

7. The rejection of claims 80-84 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for reasons of record. Applicant has not amended the claims or provided any arguments to obviate the rejection.

8. The objection of claim 80 due to dependence upon a non-elected claim is maintained.

9. Claims 54-73 are objected to because of the following informalities: the claims are dependent upon a non-elected claim. Appropriate correction is required.

10. All other rejections and objections as stated in Paper No. 13 are withdrawn.

Conclusion


11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1642

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
June 2, 2002